Attorney Docket No.: 71515.088.999
Customer No.: 35161

REMARKS

This Amendment is in response to the Office Action mailed on April 26, 2005, for the present application, which has been reviewed. Considered together with the following remarks, arguments and request for reconsideration are believed sufficient to place the application into condition for allowance. No new matter has been added to the application. Applicants express appreciation for the thoughtful examination by the Examiner.

The present invention is drawn to a vaccine composition comprising an effective amount of an isolated HP30 polypeptide of Helicobacter spp.

SPECIES REQUIREMENT

Applicant has elected species I, directed to a 30kDa polypeptide. In response to the Office action, the election by the Applicant of the claims to one species is for the purpose facilitating the search. The position of the Applicant is that if a generic claim is not allowed, that is, a claim that covers all of your different species, Applicant is allowed to claim only one species, and can file divisional applications on the non-elected species. In this present application, Applicant believes that there is a reasonable number of different species, which does not require a species election. However, Applicant has previously elected a species to facilitate the search and advance the prosecution of the case.

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Claim Rejections Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn

The term "effective amount" is defined on page on page 5, lines 31-35. The specification teaches "Methods of inducing an immune response to Helicobacter spp. and methods of preventing, treating or ameliorating disorders or diseases related to Helicobacter in a mammal, in need of such treatment comprising administering **an effective amount** of the pharmaceutical or vaccine composition of the invention".

Claim Rejections Under 35 U.S.C. § 102 Should Be Withdrawn

The rejection of claims 79, 80, 82, 83, 84, and 86 under 35 USC 102(b) as being anticipated by Tomb et al. should be withdrawn.

Tomb et al. discloses the entire genome sequence of the Helicobacter pylori. The Examiner is reminded that for the reference to anticipate, the reference must teach every element or limitation of the claims. Tomb et al. does not teach a vaccine composition, or any effective amounts to be used to prevent, treat or ameliorate disorders related to Helibacterial infections in a mammal. In fact the Tomb et al. reference teach 1590 coding sequences. Applicant is not claiming the Helicobacter genome, but are narrowly claiming one (1) single coding region for the use in a vaccine due to its unexpected immunogenicity. All claims are drawn to vaccine compositions recited in the preamble of the claims, which breaths this functional limitation into all of the claims. Tomb et al. does not disclose vaccines, and is therefore not an enabling

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reference or the use of (1) coding region for its immunogenic properties. Thus the rejection must be withdrawn.

Claim Rejections Under 35 U.S.C. § 103 Should Be Withdrawn

The rejection of claims 85 and 88 under 35 USC 103 (a) as being unpatentable over Tomb et al. as applied to claims 79, 80, 82, 83, 84, and 86 above, in view of WO 96/40893 (1996) should be withdrawn.

It is the position of the Applicant that, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. The Office action does not point to or identify any suggestions in the prior art of why this single gene product (HP30) should be selected from over 1500 gene products or provide scientific analysis why the use of only HP30 would have been obvious.

The Examiner bears the burden of establishing a case of prima facie obviousness. There are nearly an infinite number of possible combinations of the known 1590 gene products taught in the prior art. The failure of the cited references to suggest which single gene could be used as a vaccine would not have been obvious at the time of this invention, i.e. filing date. The Examiner has not met its burden of establishing the fact that the prior art would have suggested the claimed single gene product for use as a vaccine.

Accordingly, an Examiner cannot establish obviousness by locating references which describe various aspects of an Applicant's invention without also providing

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evidence of the motivating force which would impel one skilled in the art to do what the Applicant has done. In re Fine, 837. F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988).

Again, Applicant is not claiming the sequence of the gene product, but is narrowly claiming a novel use of one single gene in a vaccine. This is "obvious to try", but does not provide a reasonable expectation for success.

The Examiner is reminded of the state of the art. Immunization with H. pylori proteins including urease, heat shock protein, and catalase has resulted in vaccines that induce immune responses to H. pylori, but do not protect from colonization upon challenge with H. pylori. Therefore there is a long-felt need to develop a vaccine to protect or treat H. pylori infections by inducing immune responses to other antigens.

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CONCLUSION

In light of the foregoing, Applicants respectfully submit they have addressed each and every item presented by the Examiner in this Office Action. Favorable reconsideration of all of the claims as amended is earnestly solicited. Applicants submit that the present application is in a condition for allowance and respectfully request such allowance.

If the pending claims are not in condition for allowance, Applicant request an interview with the Examiner of Record at their first available opportunity.

If the Examiner believes that there is any issue which could be resolved by a telephone or personal interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

October 17, 2005
Date

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